



1152 '99 APR -6 10:49

April 5, 1999

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

**RE: Docket # 98D-1146** - Discussion Paper: *A Proposed Framework for Evaluating and Assuring the Human Safety of the Microbial Effects of Antimicrobial New Animal Drugs Intended for Use in Food-Producing Animals*

To Whom It May Concern:

Thank you for the opportunity to comment on the FDA discussion paper: A Proposed Framework for Evaluating and Assuring the Human Safety of the Microbial Effects of Antimicrobial New Animal Drugs Intended for Use in Food-Producing Animals.

LCI is a national organization with a mission to unify organizations, allied industries, government agencies, researchers and individuals interested in cooperatively addressing animal health, animal care and food safety issues affecting animal agriculture in North America.

The board met on April 1, 1999, and considered a unified position statement from the LCI Food Safety, Cattle Health Management, Sheep Health Management and Swine Health Management Committees addressing the use of drugs in food animals. Subsequently, the board of directors adopted the enclosed resolution.

We request that the agency consider this resolution when determining appropriate underlying concepts to be used in the development of antimicrobial approval policies protective of the public health.

Sincerely,

*Thomas W. Wenstrand*

Thomas W. Wenstrand  
Chairman of the Board

Enclosures

*98D-1146*

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# USE OF DRUGS IN FOOD ANIMALS

## BACKGROUND

The Livestock Conservation Institute recognizes that more data are needed to complete a scientific risk assessment on the public health significance of antimicrobial use in livestock. The 1998 National Research Council report, "The Use of Drugs in Food Animals: Benefits and Risks" states that, "*at this time, there appears to be no immediate risk to public health.*" Antimicrobials are used in livestock to prevent, control, or treat certain diseases, and to promote efficient growth by improving the animal's ability to convert grain and roughage into meat, milk, and eggs. Antimicrobials are an important tool in maintaining the health and welfare of food-producing animals and public health.

## RESOLUTION

The Livestock Conservation Institute supports appropriate measures to protect public health and encourages the judicious use of antimicrobials by veterinarians and food animal producers when antimicrobial use is necessary. These protective measures need to be proportional to the actual risks to public health. LCI encourages the Food and Drug Administration's Center for Veterinary Medicine to continue to approve animal health products including antimicrobials, found to be safe and effective for use in food-producing animals; and encourages the Center to base any new or additional restrictions or prohibitions of currently approved or new antimicrobials on sound, peer-reviewed scientific evidence and risk assessments developed in an open public process, demonstrating a significant impact on public health.

*Adopted by the LCI Board of Directors on April 1, 1999.*

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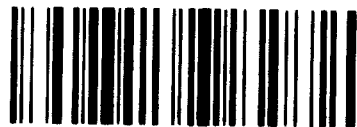
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